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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/760,515	01/20/2004	Ronald Charles Bernotas	USHMR2037 US DIV I	1497

5487 7590 04/02/2007  
ROSS J. OEHLER  
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1041 ROUTE 202-206  
MAIL CODE: D303A  
BRIDGEWATER, NJ 08807

EXAMINER
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CHANG, CELIA C

ART UNIT	PAPER NUMBER
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1625

SHORTENED STATUTORY PERIOD OF RESPONSE	NOTIFICATION DATE	DELIVERY MODE
3 MONTHS	04/02/2007	ELECTRONIC

**Please find below and/or attached an Office communication concerning this application or proceeding.**

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Notice of this Office communication was sent electronically on the above-indicated "Notification Date" and has a shortened statutory period for reply of 3 MONTHS from 04/02/2007.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

USPatent.E-Filing@sanofi-aventis.com  
andrea.ryan@sanofi-aventis.com

## Office Action Summary

**Application No.**

10/760,515

**Applicant(s)**

BERNOTAS ET AL.

**Examiner**

Celia Chang

**Art Unit**

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 10 January 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 5-8 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) \_\_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- ☒ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_
- ☐ Notice of Informal Patent Application
- ☐ Other: \_\_\_\_\_

### DETAILED ACTION

1. Amendment and response filed by applicants dated Jan. 10, 2007 together with a terminal disclaimer have been entered and considered carefully.

Claims 1-4 have been canceled. Claims 5-8 are pending.

2. The rejection of claims 1-4 under 35 USC 112 second paragraph is dropped in view of the cancellation of the claims.

3. The rejection of claims 1-4 under 35 USC 101 is dropped in view of the cancellation of the claims.

4. The rejection of claims 1-4 under 35 USC 103(a) over Scott and Heath in view of Tippins or Wilshire is now applicable to claims 5-8 and is maintained for reason of record.

The gist of applicants argument is that the Tippins or Wilshire reference provided strategies for isolating and identifying a variety of metabolites. However, the articles excerpt that these separation techniques are still complex and each case may involve a different technique. This argument is inconsistent with the amended scope of the claims.

Applicants' attention is drawn to that the instant amended claims 5-8 are drawn to general steps of separation inclusive of *any and all* conventional operable endeavor known in the art. There is no complexity, no different technique or any specifics required by the claims. Please note that Scott and Heath disclosed process of separating metabolites of (2,3-dimethoxyphenyl)-1-[2-(4-fluorophenyl)ethyl]-4-piperdinemethanol after administration to subjects. The spectrum of metabolites being separated by chromatographic technique was found on page 375 figure 4. In figure 4(d) multiple metabolites were disclosed while the first peak was identified by mass spectroscopy. Therefore, Scott and Heath generically disclosed the claimed process. The more limited scope of naming one metabolite among the many is prima facie obvious. Especially, it is well recognized in the art that for phenolic compounds such as the first metabolite of (2,3-dimethoxyphenyl)-1-[2-(4-fluorophenyl)ethyl]-4-piperdinemethanol (compound II, p.372), the recognize route of elimination is a sulfonate conjugation (see Gainsky et al.). One having

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ordinary skill in the art in possession of the specific teaching on metabolites and their separation by chromatographic method would be motivated to identify any and all of the separable metabolite of the drug employing conventional techniques provided in the art by Tippins or Wilshire. The ordinary skilled person informed by Scott and Health that the first metabolite is a phenolic compound (see compound II) would reasonably anticipate that among the many subsequent metabolites, a sulfonated conjugate would be expected. Applicants provided no factual evidence that there is any *difference or complexity* is required by the claims.

5. The rejection of claims 1-4 under the judicially created doctrine of obviousness type double patenting over US 6,465,490 which is now applicable to claims 5-8, is dropped in view of the acceptable terminal disclaimer filed by applicants.

6. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Celia Chang whose telephone number is 571-272-0679. The examiner can normally be reached on Monday through Thursday from 8:30 am to 5:00 pm.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thomas McKenzie, Ph. D., can be reached on 571-272-0670. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

OACS/Chang

A handwritten signature in black ink, appearing to read 'C. Chang', with a stylized flourish at the end.

*Celia Chang*  
*Primary Examiner*  
*Art Unit 1625*